EXHIBIT A

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION,

MDL No. 2419
Master Dkt:
1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

All Actions

VIDEOTAPED DEPOSITION OF DAVID A. KESSLER, M.D.

9:00 a.m.
March 4, 2016

Suite 2900
275 Battery Street
San Francisco, California

GINA V. CARBONE, CSR #8249, RMR, CRR, CCRR

Q. In the report?

A. And if you look at Schedule 3B, which goes on from page 254 to 324, that's all in the report. That's FDA's documents relating to shortages.

Q. Okay. And then the last two things in the stack include a definition under 21 U.S.C. 351 of when a drug or device is adulterated. Page and a line.

A. That's just 350 -- yeah, it's just the part of the statute that deals with old drugs as opposed to new drugs.

Q. Right.

And then finally, in the material you just gave me, we have two documents, FDA 428907, 428908, 428909, that reflect email communications between Bruce Ota, and Karen Archdeacon with respect to NECC.

A. That are part of the FDA FOI request that I received that was cited by Dr. Miller.

Q. What I'm going to do, Dr. Kessler, is I'm going to have my assistant here, Kaycee, put an exhibit number on each of these respective stacks while you and I continue to talk, and then we'll identify these as separate exhibits in just a moment.

A. Sure. And if I could just -- if any of your questions, I need those --

Q. Absolutely.

A. You know, I don't believe so. Maybe preventive medicine, other things -- I'm a professor of epidemiology, biostatistics. I don't know what that grants me. We'd have to look.

Q. Up to and including, if your estimate is correct, 2007, you came to -- you came to UCSF 2003, didn't you?

A. I did.

Q. Okay. From 2003 until 2007, did you actually have staff privileges at an outpatient diagnostic center?

A. We'd have to check the bylaws. As you know, UCSF has many different clinics associated, and I just don't want to use -- I'm pretty sure my privileges would have attached using the specific word outpatient diagnostic center. Certainly there were outpatient clinics and outpatient ambulatory units, and I'm sure my privileges attached to those.

Q. Well, when I use the term outpatient diagnostic center I'm being more specific than that. The term I -- the meaning I intend to convey with that is an ODC, similar to what's licensed in Tennessee, that will have the capacity to do a CT myelogram, MRI, will have the capacity to infuse Omnipaque for the purposes of diagnostic studies, in some cases they'll do

bronchoscopies.

A. Sure.

Q. Did you ever have staff privileges at an outpatient diagnostic center as I have described?

A. So I believe UCSF, my staff privileges accounted -- encumbered all the UCSF clinics. Have to go back and look at the bylaws.

Q. Okay.

A. And certainly those clinics included those -- had those kind of services available.

Q. When you came to UCSF, were you given tenure from the beginning?

A. Yes.

Q. And tenure at UCSF means what?

A. How long do you want it to mean?

Q. Good response.

Does tenure mean that you get to hold the faculty position for life if you are tenured?

A. I let others judge what tenure is.

Q. Okay. Now, your CV represents to me that you were the dean of the UCSF School of Medicine from 2003 to 2007, correct?

A. That's correct.

Q. You were fired on December 13th, 2007 as the dean of the UCSF school of medicine?

A. As a dean, but not as the professor of pediatrics.

Q. And your termination as dean of the UCSF School of Medicine was upheld by a hearing committee at UCSF on January 11th, 2010, correct?

A. So, again, I was a whistleblower in a matter, and I will leave it to others to decide what is confidential.

Q. Was your termination of December 13th, 2007 upheld by a hearing committee on January 11th, 2010?

A. I don't believe -- I believe that there are certain things that are confidential. I don't believe that that was a matter of public record, but I don't know.

Q. Let's have exhibits -- items 2 and 3.

I'm handing you Exhibit 1245, Dr. Kessler.

MR. CHALOS: What happened to the other exhibits?

MR. GIDEON: She's stacking them up.

MR. CHALOS: I'm sorry, you marked the --

MS. WEETER: I marked all those.

(Whereupon, Exhibits 1241 through 1245 were marked for identification.)

MR. GIDEON: And we'll cover those sometime in the future.

Q. Exhibit 1245 is a complaint you filed acting as lawyer for yourself in the United States District Court for the Northern District of California in the San Francisco Division.

If you look at page 18 of the complaint, you'll see your signature, correct?

A. I see my signature there. I believe the Government Accountability Project represented this.

Q. Well, I see only a David Kessler signing the complaint pro se in the complaint filed December 12, 2008.

Do you see a signature by any other lawyer?

A. No, but as I understand this, I mean, I was represented by the Government Accountability Project.

Q. Okay. Well, subsequently a summary judgment was granted in favor of the people you sued; isn't that correct?

A. This is with regard to retaliation complaints.

Q. Well, with respect to the entire complaint.

A. But if you read your question, your question was whether my firing was upheld. This is whether there was retaliation.

Q. Well --

A. Under the civil rights law.

(Whereupon, Exhibit 1246 was marked for identification.)

MR. GIDEON: Q. I'm handing you Exhibit 1246, which is the Order Granting Defendants' Motion for Summary Judgment: Requiring Plaintiff's Opposition Papers to be Filed in an order entered October 5th, 2011 by Phyllis J. Hamilton, United States District Judge.

This dismissed your complaint, did it not?

A. There was a -- if you read the last opinion of her -- the last paragraph, there was -- what she dismissed, not on the merits, but she dismissed my grievance, which was a retaliation grievance.

Q. Okay.

A. Under the whistleblower, again, the Civil Rights Act.

Q. If you'll look at page 8 of that summary judgment order that's in front of you?

A. Yes.

Q. Focus right there on page 8, you will see the finding by the United States district judge that on January 11th, 2010 --

A. Show me which sentence you are at.

Q. It's the first full paragraph on page 8 of the opinion. Page 8 of 25.

A. Right.
Q. It states, quote: On January 11, 2010, the Hearing Committee issued its finding of fact, conclusions and recommendations.
And then there's a citation to certain documents.
A. Yes.
Q. And then it says: The Hearing Committee unanimously concluded that Dr. Kessler's Grievance should be denied in its entirety.
A. The whistleblower -- the retaliation grievance. I was labeled as a whistleblower. That was agreed to, and they denied retaliation.
Q. Then it says: The Hearing Committee found that "the reason for Dr. Bishop's decision, in consultation with his superiors, to terminate Dr. Kessler from his Deanship was not retaliation for Dr. Kessler having made protected disclosures. Rather, Dr. Bishop's decision reflected his view that Dr. Kessler could no longer effectively lead the School of Medicine."
I've read that correctly, have I not?
A. You have.
Q. All right. Wasn't this summary judgment order the termination of the litigation between you and the University of California at SF?

A. This is exactly what this represents.
Q. It is what it is, hah?
A. It is what it is.
Q. Okay. Have you had any subsequent litigation with UCSF over your relationship with that institution?
A. Again, we'd have to check with the Government Accountability Project, but I don't believe so.
Q. Have you had any other personal litigation against lawyers, doctors, or corporate entities?
A. No.
Q. Have you had any other personal litigation --
A. Excuse me. At what point in time?
Q. Any time.
We found this on Pacer, which you know is the federal court system. Have you had any other litigation against another medical school --
A. No.
Q. -- during your career?
A. No.
Q. Have you had any litigation against a company or an individual over another dispute during your career?
A. During my career in my professional capacity?
Q. Yes.
A. No.

Q. Have you had any litigation with any law firms over your testimony or your fees?
A. No.
Q. Okay. I mentioned earlier, when we first started talking, that the FDA website reflects that you were the commissioner of the Food, Drug and Cosmetics Agency from November 8th, 19 --
A. Food and Drug Administration.
Q. Okay. Food and Drug Administration.
A. Please.
Q. I'll get it.
A. Thank you.
Q. The website reflects your tour of duty was November 8th, 1990 to February 28th, 1997. Does that sound correct?
A. Again, that sounds correct. That was probably -- we have to check when I became -- officially it was confirmed. I probably didn't start until December, I think I mentioned to you.
Q. You did.
When did you actually become employed by Yale University?
A. Probably July 1st, 2000 -- I'm guessing July 1st, 1997.
Q. When you left the FDA, did you already have, in

hand, an offer to join Yale?

A. No, I did not. I deliberately didn't -- I had no contact with Yale prior to FDA.

Q. Do you remember my request at the beginning that I ask succinct questions and you give me a succinct answer? I'd like to ask it again.

When you left the FDA, did you have a job offer in hand from Yale University?

MR. ARBITBLIT: Objection. Asked and answered, Counsel.

THE WITNESS: If my answer was -- is direct as I could be, was no, I did not.

MR. GIDEON: Good.

THE WITNESS: I mean, it's on the record.

MR. GIDEON: Q. Okay. How long did it take you before you found employment after leaving the FDA February 28th, 1997?

A. I think in a matter of days. I think that weekend, if I'm right. I don't remember exactly which weekend it was, I recall coming home from the dry-cleaner and my wife saying Rick Levin called and he asked whether you want to be dean of Yale Medical School.

Q. Was Rick Levin the chairman or chancellor of Yale University?

A. He was the president. So I think it was a matter of very soon thereafter. That call from Rick was unsolicited.

Q. Okay. You handed us, and we're going to exhibit them in a few moments, two green binders that reflected correspondence from a lawyer on your behalf to Dr. Miller.

A. And --

Q. And --

A. And a letter from me to Dr. Miller.

Q. Fine. I haven't had a chance to look at them. I haven't had a chance to read the pages, so I don't know the content.

A. Uh-huh.

Q. But you did mention, when you were describing them, there was some kind of either formal or informal audit document attached to one of the letters.

Do you recall that?

A. Yes.

Q. Okay. Was there an evaluation audit or examination of your billing the FDA for travel-related expenses at the time you left on February 28th, 1997?

A. Can I have those documents?

Q. Sure.

A. So as I -- as I remember --

Q. Hold on just a second so I can hand you the documents.

A. Thanks.

Q. I'm going to hand Dr. Kessler two documents right now. One is entitled Exhibit 1240 that begins with a letter of July 25th, 2003 to Dr. Henry Miller. That's the first page.

Then there is a second exhibit, 1239, that has the same letter in this folder.

And here are those two back.

A. Thank you, sir.

Q. And the pending question, Dr. Kessler, is whether when you left the FDA, was there an audit underway to determine if you had appropriately accounted for travel expenses?

A. No, I don't think that -- I don't think -- as you phrased the question, the answer would probably be no. But let's look at this letter because this probably has the information.

Q. In exhibit which number?

A. Well, there is -- if you take Exhibit 1237 (verbatim), and if you look at this January 24th, 1997.

So let me give you a little more context for your -- to the answer to that, best I can do this.

So there is -- there was first a -- we can make

this very simple.

Q. Good.

A. I was not involved with -- as this finding shows, I was not involved at all with my travel vouchers. I didn't -- as this says, I did not personally handle my travel vouchers or imprest fund transactions. I provided receipts or -- when it was requested, but I wasn't involved in the details reviewing and signing vouchers or transactions.

But I was -- but so -- but I did -- I requested, in 1993, if you look, late 1993 or 1994, just as a matter of prudence, the Office of Financial Management reviewed his vouchers to assure compliance with regulations, and a review found them to be in order.

So the first time I just -- I voluntarily -- I just said please, just review all my travel, and they did. And then I think what the history was -- and again, you have to trace this. But there was some -- I think it's in my book. There was some 650 FOI requests on me. And you can trace it through an outside third-party group that requested just, again, hundreds of requests for documents.

That, if you look, I think you can -- if you connect the dots, that was -- we were involved in --

it's about investigation of the tobacco industry and there were connections to that group with the tobacco industry.

I don't know the full -- I've never been privy to the full handoff of that group as a result of the tobacco industry engaging with that group and monitoring things and then handing it off.

But then it says in February of 1996, a congressional inquiry into my travel eventually spurred interest in the Associated Press. The congressional inquiry was limited. I asked the scope be expanded to a complete audit of his travel documents. The commissioner asked that the audit be conducted at a level of detail beyond which was normally devoted, and then steps were taken.

And then the audit of the six years travel vouchers and imprest funds from 1991 to 1996 -- so this was done before I left -- reveal 275 taxi claims with a total reimbursement of $8,000. And then it talks about an over-reimbursement of 823. But that was done at the time.

Bottom line, though, is this demonstrates I was not -- I had nothing to do with my travel expense forms whatsoever.

Q. I didn't ask you to admit complicity. I just

wondered if there was an audit underway when you left.

A. So the answer is no. It looks like the audit was complete.

Q. Okay.

A. And there was several audits done, some at my request, as this lays out.

Q. You graduated from law school in what year? Not that long ago. At least for me it's not that long ago.

A. So I probably -- I graduated, what, I did two years at University of Chicago and a third year at Harvard. So Harvard was '78.

Q. Okay. Have you ever been licensed to practice law in any state?

A. Never sat for a bar. Chose not to take a bar.

Q. So the answer is what?

A. Never took a bar.

Q. So never licensed to practice law anywhere in the United States?

A. Because I never took a bar, yes. I graduate -- have my law degree.

Q. You've never taken a deposition, argued a motion in court under the authority of another lawyer, have you?

A. No, but I've taught law school.

I feel more comfortable than others --

MR. GIDEON: Q. Right.

A. -- discussing. Because -- so just hand me the standards and I'd be happy to tell you which ones I'm comfortable doing.

Q. Okay. Now, where is there any statement on page 3 of the document that I handed to you, that exhibit that has methylprednisolone acetate at the top, where it says this can only be dispensed with a patient-specific prescription?

A. Well, so this says -- so the answer is this does not say those exact words, as you've stated. It does say, if you look at three bullets from the bottom, that it is compounded for your patients by pharmacists extensively trained in aseptic compounding.

The definition of compounding, right, certainly -- almost every definition of compounding means that the drug is -- if it's compounded, it's available for an individual patient by an individual prescription subject to a physician/patient relationship. So that's the basis of compounding.

Q. Okay. Is there a difference between aseptic compounding versus terminal sterilization?

A. I'd want to review that.

Q. Let me ask it differently. Do you know of any

difference between aseptic compounding and terminal sterilization?

A. I'd want to look at the various standards before I gave an opinion.

Q. Do you have any information at all whether the terms are synonymous or different, as you and I speak now? And the terms I'm talking about are aseptic compounding on one hand versus terminal sterilization on the other.

A. Yeah. So I, obviously, was involved in major sterility issues. And sterility is part of the Food, Drug and Cosmetic Act. I'd want to look at the code before I give an opinion.

Q. What is a class 10 microenvironment?

A. I'd have to look that up.

Q. How does a class 10 differ from an ISO 5 or an ISO 7 microenvironment?

A. Happy to look that up.

Q. Don't know without looking?

A. Again, I'd be happy -- those things are easy to answer your question. Again, happy to do that right now if you would like me to.

Q. What I'm interested in is whether you know without being prompted by looking at something else.

A. Sir, I'm here as an expert. And again, if you

look at my report, I don't go into this. You are asking me questions that are beyond my report. Happy to give you the answers, but in order to do that as an expert, I'd want to make sure. I'm not going to do stuff off the top of my head.

Q. Well, let me ask you this, Dr. Kessler: Can you tell me, without doing some research in writing, what the difference between an ISO 5 versus an ISO 7 microenvironment is?

A. I'd have to look that up. I don't carry that in my head.

Q. All right. What and how is hyaluronidase used? Perhaps you can pronounce it better than I can.

A. Hyaluronidase.

Q. Yes. I like your pronunciation. It's on page 4.

How is that used and what is it used for?

A. So hyaluronidase -- I believe hyaluronidase is usually found in collagen. I believe it's a by-product, and is an enzyme that would affect collagen. Happy to look up the biochemistry.

Q. I'm not interested in this cellular action, but in what circumstances would a physician use preservative-free hyaluronidase?

A. So I would want to look at the label for

hyaluronidase. If you have it, give it to me. And the way we would determine that is look at the label for hyaluronidase and see what it would be indicated for. Again, I don't carry it in my head.

Q. Don't know?

A. I'd want to see what -- it's very easy to get the answer. We'd look at a label and see what the indications for use would be.

Q. Okay. Now, looking at the advertisement by NECC, page 4, the one we were just looking at, is there any statement that these products are only available with a patient-specific prescription?

A. Again, as I stated on the prior page, certainly any -- it says these are compounded.

Q. Right. But my question is specific. Is there a statement these products are only available with a patient-specific prescription? It's a yes or no.

A. So --

MR. ARBITBLIT: Objection. Objection. You interrupted his answer.

MR. GIDEON: Yeah.

MR. ARBITBLIT: It's not necessarily yes or no. So object to the question being misleading.

THE WITNESS: So if the definition of compounding includes patient-specific prescriptions as

it does, if drugs are available for compounding by patient -- I mean, compounding is done for patient-specific prescriptions. So those things are -- certainly compounding includes patient-specific prescriptions.

So I would certainly say that anybody looking at this, if you know it's compounded and if you're -- if you're a professional, you should know that it's a patient-specific prescription.

MR. GIDEON: Q. I see. Is the language anywhere on this page where it says this product is only available with a patient-specific prescription, question mark?

A. On this page, it says it's compounded.

Q. Yeah.

A. Doesn't say -- have that language. I believe that if you look several pages later, it's there. But it's not -- it says it's compounded, which means patient-specific prescription.

Q. Right. Next page, page 5, starts off with Trouble Finding Preservative-Free Kenalog.

Do you see that?

A. Yeah, I do. It's triamcinolone, right?

Q. Right. It also states here, as it did on each one of the prior pages, USP 797 compliant, correct?

document which begins on page 9 with General --

MR. ARBITBLIT: I was just about to do that.

MR. GIDEON: -- General Overview of Policies & Procedures for Compounding Sterile Products at NECC.

MR. ARBITBLIT: Fair enough. That's just what I was about to do, Counsel.

Starting at page 9 of the document, General Overview of Policies & Procedures for Compounding Sterile Products includes paragraph G on the following page. Quote: Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility, end of quote.

MR. GIDEON: Okay. Now are you going to read the rest of pages 9 and 10?

MR. ARBITBLIT: I've read what I wanted to read. If you want to read more, you are welcome to do that.

MR. GIDEON: Okay. So the rule of completeness is not requiring you to spend your time going on the entire content of the document.

MR. ARBITBLIT: The rule of completeness does not mean that either of us has to read 33 pages into the record, Counsel, and you know that quite well.

MR. GIDEON: You got it. I agree.

Mr. Arbitblit to you in the summer of '14 the first time you had worked with him?

A. No, I don't believe so.

Q. Let's take a look at Exhibit B to your report --

A. Sure.

Q. -- which is a listing of litigation-related involvements.

A. If you want to just see, it is --

Q. I'm going to hand you one. Don't worry about it.

A. Thanks.

Q. We're going to hand you one.

And for the purposes of efficiency, I'm going to refer to the firm you are working with today as Lieff Cabraser. There may have been name changes over the years, but that's the firm I'm referring to.

Mr. Arbitblit is a member of Lieff Cabraser, correct?

A. Yes.

(Whereupon, Exhibit 1248 was marked for identification.)

MR. GIDEON: Q. Okay. This is Exhibit 1248, and it's Exhibit B to your testimony?

A. Yes.

Q. The first thing I want to do is for you to tell us on the bullet points in which of those cases were you employed, contacted to participate in the case, by Mr. Arbitblit or one of his colleagues at Lieff Cabraser?

A. Give me a second to go through this list to find that.

Q. Sure.

MR. CHALOS: Object to the form.

MR. GIDEON: What's wrong with the question?

MR. CHALOS: It's compound. It says in which of those cases were you employed, contacted to participate in the case. I think those are two different concepts.

MR. GIDEON: Well, we'll see if we can bridge that gap.

MR. CHALOS: That's a good idea.

MR. GIDEON: Q. Ready?

A. Yeah. Thank you.

Q. In which of the cases were you contacted to participate by Lieff Cabraser or one of the lawyers in that office?

A. My recollection is that I was contacted in the Yaz case by Mr. Arbitblit.

Q. Okay. This is six bullet points down, the Yaz

and Yasmin Marketing Sales Practices & Products Liability Litigation?

A. Yes. My recollection is I was contacted by him.

Q. Did you end up working with him in that litigation or did you work principally with someone else?

A. There were multiple attorneys involved in that case.

Q. Okay.

A. That case settled.

Q. Any others?

A. So the answer is -- I just want to be complete. I'm going to go a little beyond your question, if I may, okay, I mean, so you have the full -- so I don't misspeak here, right?

I believe the -- there's two other cases that come to mind where Mr. Arbitblit may have been involved in, but I don't believe he contacted me.

Q. Okay.

A. But again, of one I'm sure he didn't contact me because it was the attorney general of Louisiana where I was retained on, but I believe Mr. Arbitblit worked on that. And there may have been -- and --

Q. Which one was that on this list?

A. So there was -- it was State v. -- if you go down, State v. Merck, that's the attorney general of Louisiana.

Q. And Mr. Arbitblit, according to your recollection, worked on State versus Merck & Company?

A. Yes, that's my recollection.

Q. Okay. And is there another one where you think you worked with Mr. Arbitblit?

A. Yeah. Again, I don't remember who -- I mean, that one I know Mr. Arbitblit did not contact me on.

Q. Okay.

A. I can recall. But I believe Mr. Arbitblit was involved in Actos, but I don't recall who contacted me.

Q. Which bullet corresponds with that reference? The one that's near -- two-thirds down?

A. Yes, sir.

Q. Okay. In the Western District of Louisiana, filed 12/29/11?

A. Yes, sir.

Q. Okay. Now, I didn't mean to limit my question to Mr. Arbitblit. I intended to expand it to all the members of his law office, Lieff Cabraser, irrespective of which office it may be. Are there any other cases where Lieff Cabraser worked with you on this Appendix B?

A. Let me look. Those are the ones that I see

sitting here.

Q. Okay.

A. That's the ones -- that's what comes to mind.

Q. Now, I just want to take them item by item so we get a snapshot of what the case was about from your view.

On the Zoloft Product Liability Litigation that was filed April 17th, 2012, were you testifying on behalf of the people suing the manufacturer of Zoloft?

A. Yes.

Q. And who was the manufacturer of Zoloft that you were offering opinions about?

A. I'd have to -- I believe it was Pfizer.

Q. Okay. And at the time that Pfizer developed Zoloft, was Pfizer an FDA-registered manufacturer?

A. Certainly.

Q. Did you express the opinion that Pfizer, as an FDA-registered manufacturer, had acted improperly?

A. We'd have to pull that. You would have to look at that.

Q. You don't recall what the critique was?

A. I --

Q. Sir? You don't recall --

A. I'm just double-checking that it's Pfizer. Just to be -- just so that I have my head -- just give

me one second.

That case had to do with birth defects and what the label said about -- and whether it was appropriately categorized as a category D drug, whether there was human evidence. And there was human evidence, and I said that.

Q. And the essence of the critique was that the manufacturer of Zoloft had not shared with the FDA the data reflecting that the product could be harmful to the unborn, correct?

A. No. I don't think that was what the critique was.

Q. Well, what was it, then?

A. So I -- well, we'd have to pull the actual opinions, and I don't have that with me.

I think that the critique was that the -- that the human evidence of risk to the fetus was not disclosed to patients and physicians in the label. Not to -- not as you said.

Q. All right. The second bullet point, In re Risperdal -- Risperdal. Excuse me. Risperdal is manufactured by Johnson & Johnson, isn't it?

A. Janssen Pharmaceutica is owned by Johnson & Johnson.

Q. What was the critique of the division of

Johnson & Johnson in re Risperdal?

A. This had to do with boys growing breasts and the issue of both the -- as you know, there was a -- there was a criminal trial with off-label prosecution for Janssen. I believe an off-label promotion.

So it had to do with both the off-label promotion, that illegal activity, as well as whether Janssen failed to disclose data in the scientific -- I mean, in its studies.

Q. Uh-huh. You offered opinions critical of the division of Johnson & Johnson in that case, didn't you?

A. I offered the opinions, the facts supported.

Q. I am not -- I am not asking you whether you felt your opinions were justified or somebody didn't. I'm just trying to determine which side of the litigation you were on, Dr. Kessler.

Were you testifying on behalf of a patient suing Janssen or were you testifying on behalf of Janssen?

A. On behalf of the patient.

Q. All right. Let's go to the third bullet point, Wells versus Allergan, Drake versus Allergan, two cases listed together. What was the essence? What was the issue in these cases?

A. So the issue was children getting botulism from

Botox.

Q. Were you testifying on behalf of a family suing Allergan or were you testifying on behalf of Allergan?

A. I was testifying on behalf of the families where the children got botulism.

Q. And at the time Allergan made the products in question, Allergan was an FDA-registered manufacturer, correct?

A. Yes.

Q. Let's go to the fourth item, fourth bullet point, C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation. Did this deal with the pelvic sling?

A. Pelvic mesh.

Q. And in that case were you testifying on behalf of patients suing C.R. Bard?

A. Yes.

Q. And at the time C.R. Bard made the pelvic mesh, was C.R. Bard an FDA-registered manufacturer?

A. I'm sure.

Q. Okay. Then the next bullet point is SB versus Ortho-McNeil-Janssen Pharmaceuticals, Risperdal. Ortho, McNeil and Janssen are all wholly-owned subsidiaries of J&J, aren't they?

A. Yes.

Q. Were you testifying on behalf of patients suing Ortho, McNeil and Janssen?
A. Yes.
Q. Ortho, McNeil and Janssen were all FDA-registered manufacturers, correct?
A. Yes.
Q. In re Yaz & Yasmin Marketing Sales Practice & Products Liability Litigation. Yaz and Yasmin were contraceptives, weren't they?
A. Drospirenone. Yes, sir.
Q. And who was the company that made those products?
A. I'm just double-checking so I can get -- my recollection is it's Bayer. Let me just double-check that for the record.
Yes, it's Bayer HealthCare Pharmaceuticals.
Q. Was Bayer HealthCare Pharmaceuticals an FDA-registered manufacturer when Yaz and Yasmin were made?
A. Yes.
Q. And what was your critique of Yaz and Yasmin?
A. Again, I think it had to do with off-label activity as well as disclosure of -- the failure to disclose data that the company had.
Q. Failure to disclose data the company had before

seeking approval?

A. We'd have to pull the report. I don't want to misspeak here.

Q. All right. In re Flonase Antitrust Litigation, who engaged you in that case? Which side of the litigation?

A. There were corporate entities that engaged me. These were payers who paid for drugs. This was antitrust litigation.

Q. And your role was to support people who were opposing a merger?

A. No. This was complicated citizens' petition language, generic -- generic drugs, et cetera. I was testifying on a pretty narrow issue.

Q. And what was the narrow issue?

A. Again, about FDA citizens' petition, the regulation of generic drugs.

Q. I see. Okay.

Well, did you offer substantive testimony regarding the scope of FDA regulation of generic drugs in that case?

A. I think that would be probably fair. We'd have to go back and look at the testimony.

Q. That was the Eastern District of Pennsylvania?

A. Right.

Q. Okay. Is Pharmathene versus Siga Techs, Inc. a commercial case?

A. Yes.

Q. Does that also deal with market share, antitrust considerations?

A. No. I believe it had to do with patent. I was hired by Siga Technologies, the -- I was hired by the drug manufacturer.

Q. Commonwealth versus Merck & Company, Kentucky Circuit Court, September 28, 2009 and Utah; what product was at issue in that litigation?

A. That was I was retained by the attorney general of the state. And that was Vioxx.

Q. Vioxx. Okay.

And you were testifying on behalf of individuals suing Merck & Company?

A. No.

Q. No?

A. I was testifying on behalf of the attorney general.

Q. And the testimony you offered at the request of the attorney general was what?

A. I mean, it had to do with the science underlying Vioxx.

Q. Did it have to do with the risk of myocardial

infarction in individuals taking Vioxx?

A. Yes.

Q. And did you offer the opinion that Merck & Company had not acted appropriately with respect to the risk of myocardial infarction?

A. There was specific -- I'd want to look at that report, but there were specific representations of the company that were in question.

Q. Your testimony was critical of Merck & Company?

A. My testimony dealt with that science. And again, happy to come back and tell you what those opinions were. I believe that case settled, so I don't know what's public record or not.

Q. Merck & Company was an FDA-registered manufacturer at the time that it's -- that it developed and obtained permission to market Vioxx in the United States, wasn't it?

A. Yes.

Q. Okay. Next one is Commonwealth Care Alliance versus AstraZeneca Pharm, L.P. Is this a commercial dispute over insurance payments or market share?

A. I believe this is -- this is also -- I'd want to go back. I believe this was an antitrust case.

Q. Smith & Nephew, Inc. versus N.H. Insurance Company in the Western District of Tennessee. What was

the issue there?
A. I was retained by counsel for the defendants. Again, it had to do with legality of conduct.
Q. The legality of Smith & Nephew, Inc.'s conduct?
A. Yes.
Q. Was there a contention by N.H. Insurance Company that they shouldn't have to pay for something because Smith & Nephew had done something inappropriately?
A. Again, I want to be a little careful. I don't know what is confidential there and what's not. So we'd want to check with counsel before I answer.
Q. Who was the attorney that engaged you in the Smith & Nephew case?
A. Frost, Todd, Brown.
Q. In Kentucky?
A. Yes.
Q. Who in particular at Frost Todd engaged you?
A. Laurie Hammond.
Q. Say it one more time.
A. I believe Laurie Hammond.
Q. And who was the attorney for Smith & Nephew, Inc.?
A. I don't recall.
Q. Okay. In re Neurontin Marketing, Sales

Practices & Products Liability Litigation, the District Court of Massachusetts.

A. Again, legality of conduct, off-label promotion by Pfizer, certain corporate entities suing Pfizer for that off-label conduct.

Q. Right. And Pfizer, again, was FDA registered at the time they carried out the conduct in question, weren't they?

A. Yes.

Q. Did you work with Lieff Cabraser in the Neurontin Marketing Sales Practices & Products Liability Litigation?

A. That does not come to mind, no.

Q. Brown versus American Brands, is that a tobacco case?

A. That is.

Q. In re Actos, who was the manufacturer of Actos?

A. I believe it was Takeda.

Q. Takeda. Japanese pharmaceutical firm?

A. Yes.

Q. And the contention is that Actos triggered an unacceptable incidence of bladder cancer; isn't that right?

A. There was a statistically significant increase in bladder cancer if you did the analysis beginning in

2002, and that was never reported by -- that was never reported by the company.

Q. Was Takeda an FDA-registered manufacturer when they developed Actos and obtained permission to market that product in the United States?

A. Again, I would assume so. That company was acquired, I believe. I just have to go back and look. I believe that's correct.

Q. All right. The -- this is one of the cases where you said that you worked with or were contacted by Mr. Arbitblit.

A. Arbitblit.

MR. GIDEON: I'm sorry, it's hard for me to pronounce and I don't know why. Arbitblit. I've got it down now.

MR. ARBITBLIT: You are not the first.

MR. GIDEON: Q. Did you testify on behalf of patients who were suing Takeda in that case?

A. Yes. There was a $7 billion verdict.

Q. Mr. Arbitblit did very well in that case, didn't they? Did he share any of those proceeds with you after you delivered a $7 billion verdict?

MR. CHALOS: Object to form.

THE WITNESS: It was a $6 billion verdict, and no.

MR. GIDEON: Q. Next, Brown versus RJ Reynolds Tobacco. Tobacco case?

A. Yeah, I believe -- yes, it's a tobacco case.

Q. I'm going to go down to Cabana versus Stryker. Were you testifying on behalf of someone suing the device manufacturing company Stryker?

A. Yes.

Q. And what was your critique of Stryker?

A. Again, I don't know whether that is public or not. You'd -- I would want to -- I'd want you to contact the counsel. I believe that case settled, so I don't know what is public, sir.

Q. You represent -- you articulated the interest of the plaintiff or the defendant in that case?

A. I represented the interests of me, in that I told what the science was.

Q. Who engaged you, plaintiff or defendant?

A. Plaintiffs. Thank you.

Q. Who paid you, plaintiff or defendant?

A. It was a plaintiff in that case.

Q. Who was the lawyer, then, that engaged you so I can check with him and see if it's okay to talk to you about what you did in that case?

A. I'll get you the name. It's --

Q. Just make yourself a note, and when it comes to

you --

A. Yeah, it's -- it's Estephan -- it's -- first name is Estephan. Cynthia Garber was also, I think, involved. But it was Estephan. I'd be happy to get you the name.

Q. Sure. That's fine. Then the next one down is re Fosamax litigation.

A. That was a narrow issue about preemption. And -- in Fosamax. But it was whether, in fact, certain actions were preempted under a statute.

Q. Were you offering testimony on behalf of a patient suing the manufacturer of Fosamax claiming that the state law claims were not preempted by federal law?

A. Yes. It was under preemption. And, again, the nature of those claims.

Q. And you were engaged by the plaintiff in that case?

A. Yes.

Q. In any -- has there been any personal injury case in the last six years where you testified on behalf of a defendant?

A. Personal injury, no. But other cases I've testified on behalf of defendants.

Q. Well, now let's look at the affidavits here. The DePuy --

A. That's actually not true.
Q. Which one of these, where there's a claim of personal injury, death, physical suffering, where you testified on behalf of a defendant?
A. The second one.
Q. The Risperdal?
A. I'm sorry. I apologize. I'm looking at the bottom three, sir.
Q. Well, the bottom three are just affidavits or sworn expert statements.
A. They're sworn statements, but that was on behalf of the defendant, in that -- where the defendant was being sued.
Q. Which case?
A. The Cordero v. Endoscopy. I was testifying on behalf of the endoscopy center.
Q. What testimony were you offering? What was the subject matter of your opinion testimony in that case?
A. Adverse events. Adverse event reporting.
Q. Okay. Under the MedWatch system?
A. Exactly.
Q. Were you offering any testimony regarding how to perform an endoscopic procedure? On the techniques of endoscopy?
A. Not that I recall.

Q. On the first affidavit, the ASR Hip System Cases, were you offering opinions critical of that subsidiary of Johnson & Johnson?

A. There was an issue there, I believe, about public disclosure of whether certain documents in the public interest should be disclosed or not. I think that was the matter.

Q. Did this --

A. I don't recall that.

Q. Did this particular hip system case deal with petrochemical -- a failure to clean off petrochemical substances on the acetabular cup?

A. No, I don't believe so.

Q. And what was the issue in Jenkins versus Medtronic?

A. I apologize. I don't remember.

Q. It's also in the Western District of Tennessee?

A. Yes.

Q. Were you engaged by Frost Todd in that case too?

A. I don't believe that was the case. And I apologize, I don't remember that.

Q. Are there any other cases that constitute affidavits or sworn statements or testimony at trial or by deposition other than what we've just covered in this

exhibit?

A. This is what comes to mind. Actually, hold on one second. Let me just think of something.

So there may be a case subsequent to this report that I may have testified in.

Q. This report was sent to us in December of 2015. Have you testified in the last 90 days?

A. I believe I may have one case, I believe.

Q. Where?

A. In deposition.

Q. In San Francisco, but where was the case pending?

A. I believe it's St. Louis.

Q. What was the style of the case? The who sued whom?

A. It's a plaintiff -- it's a joint -- it's a bellwether case on Depakote.

Q. And who is the manufacturer of Depakote?

A. Give me a second so I can get it.

Q. Are you referring to Google again?

A. Well, yeah. I just want to make sure I get it exactly right. Just give me a second. I have it in my head, but I just -- let me -- I'll be happy to do that at the next break and give it to you.

Q. All right. Did you testify on behalf of the

manufacturer of Depakote or on behalf of people suing Depakote?

A. It was on behalf of the plaintiffs.

Q. And who engaged you?

A. There is a -- I mean, there's -- I believe there's an MDL that Janet Arbitblit and Williams Keker (phonetic).

MR. ARBITBLIT: Sorry --

MR. GIDEON: Q. Is that -- Janet Arbitblit, is that Don Arbitblit's wife?

A. No, no, no.

MR. ARBITBLIT: Janet Abaray --

THE WITNESS: Janet Abaray. I'm sorry. Now you have me confused.

MR. ARBITBLIT: My wife would not be happy to hear that there's a Janet Arbitblit.

THE WITNESS: Yes, I'm sorry. I apologize. Now you have me --

MR. GIDEON: Q. Putting aside the humor now, who was it that asked you to be involved in that case?

A. I think it's Janet Abaray.

Q. Could you spell the last name for us.

MR. ARBITBLIT: A-B-A-R-A-Y.

MR. GIDEON: Q. And where does she

practice?

A. I believe somewhere in Ohio, if I'm right.

Q. And is there, as you said, an MDL on damages associated with the use of Depakote?

A. There is -- this -- again, this is birth defects. This is a well-known teratogen.

Q. And you offered opinions in that deposition that were critical of the manufacturer of Depakote?

A. I offered an opinion of -- based on the scientific evidence that the congenital risks -- total congenital malformations was known as of a certain date.

Q. And that the --

A. And that there was also illegal -- again, there was illegal conduct. There was a consent decree against the pharmaceutical company for off-label marketing.

Q. And was this -- was this manufacturing company an FDA-registered manufacturer that carried out this illegal activity?

A. Yes.

Q. FDA registration, then, does not assure that the public will receive safe, uncontaminated products, does it?

A. No. There is no guarantee here. Right? It's a system of regulation. But as we all know, it is the -- there are no guarantees. My predecessor, Don

prohibited it or was contraindicated or something like that.

Q. Physicians are free to use medications beyond the labeled authorized uses, correct?

A. So FDA's position, okay, is as you state. Okay. There are other constraints on physicians to use drugs off-label beyond FDA regulations.

Q. There's an explicit provision, 21 U.S.C 396. Give me that.

(Whereupon, Exhibit 1249 was marked for identification.)

MR. GIDEON: Q. This is Exhibit No. 1249. You are familiar with that --

A. Let me just.

Q. -- provision of the United States Code, are you not?

A. Let me just take a look at it.

Q. Sure.

A. What's your question?

Q. Doesn't this recite the fact that nothing about the law pertinent to the Food and Drug Administration has any impact on the prerogative, the discretion, of a healthcare practitioner to prescribe or use a drug or device?

A. No, that's not --

MR. CHALOS: Object to the form.
THE WITNESS: That's not what that states.
MR. GIDEON: Q. What does this state then, Dr. Kessler?
A. So this applies, as I read this, only to devices.
Q. Okay. Have you ever researched that issue?
A. I've written extensively on the issue of off-label promotion, and I implemented the law when I was FDA commissioner.
But this has nothing -- you see the word drug here? You handed me that saying that was drugs.
Q. Right.
A. Do you see anything about drugs there?
Q. I've gotten your interpretation.
A. No, no, no. That's not my question. There's no interpretation. My question is, doesn't say the word drug there, it says device.
Q. I see. Is the FDA's position that a physician may use a device for an off-label purpose --
MR. CHALOS: Object to the form.
MR. GIDEON: Q. -- as well as a drug?
A. That's a complicated question.
Q. So there's not a straight answer to it?
A. No. I mean, I've written about this. Let me

question.

THE WITNESS: I'll wait for a question.

MR. GIDEON: Q. Isn't it true, also, that any time a pharmaceutical company has reason to know that the risks of a drug may result in adverse events, that pharmaceutical company has a responsibility to inform physicians and healthcare providers?

A. Certainly under 505.

MR. ARBITBLIT: Let's take a lunch break.

THE WITNESS: Certainly under new drug provisions.

MR. GIDEON: Q. Take a look at paragraph 326 of your --

MR. ARBITBLIT: Counsel, are you reneging on your offer to take a break whenever we wanted?

MR. GIDEON: No, I'm not. But he said under 505, and there's no such qualification on his prior testimony.

Q. Isn't it correct --

And then we'll take a break.

MR. ARBITBLIT: Okay.

MR. GIDEON: Q. -- that paragraph 326 of your affidavit says precisely what I suggested with no such qualifications?

(Whereupon, Exhibit 1250 was marked for identification.)

MR. CHALOS: What exhibit are we looking at here?

MR. GIDEON: He's got it in front of him.

MR. CHALOS: What's the number on that?

MS. WEETER: 1250.

MR. CHALOS: 1250?

MS. WEETER: Uh-huh.

MR. ARBITBLIT: And what paragraph?

MR. GIDEON: 326.

THE WITNESS: So what you are missing, Counselor --

MR. GIDEON: Q. I didn't ask you what I'm missing.

A. I'm answering your question.

Q. Is there any such qualification in paragraph 326 of the affidavit --

A. I'm answering your question.

Q. -- is the question.

MR. CHALOS: Object to the form. Argumentative.

THE WITNESS: The -- this has to do with adverse events on the drug's labeling. Those requirements are set out, right, by 505, which applies

to new drugs.

MR. GIDEON: Q. Uh-huh. Is there any reference to section 505 of the Food, Drug and Cosmetic Act in paragraph 326 --

A. No, but I'm --

Q. -- of that lengthy statement?

A. No, but I'm sure the whole report is predicated on a 505 drug -- and section 505 is, I'm sure, cited in this report.

MR. ARBITBLIT: And for completeness, the paragraph just before what you read, Counsel, refers specifically to the Food, Drug and Cosmetic Act.

(Reporter clarification.)

MR. ARBITBLIT: Paragraph 325 of the document from which counsel read refers to the Food, Drug and Cosmetic Act in its entirety. And so to read 326 in isolation is incomplete. Pursuant to Rule 106, rule of completeness, that's appropriate to add.

Let's take a lunch break.

MR. GIDEON: We're going to take a lunch break. It's -- it is 12:35 locally.

MR. ARBITBLIT: 2:35 Nashville time.

MR. GIDEON: 12:35 locally. And we'll take, what, one hour?

MR. ARBITBLIT: If you need it.

then you should not be a compounder.

The essential definition of compounding has to have -- I mean, I assume it's on the first page of the compliance policy guide. The first beginning. It's all about patient-specific prescriptions.

Q. Okay. Well, what's the definition of a manufacturer?

MR. CHALOS: Object to the form.

THE WITNESS: Under what purposes? For what purposes?

MR. GIDEON: Q. What is the definition of a manufacturer to making large volumes of drugs?

MR. CHALOS: Object to the form.

MR. GIDEON: Q. What are the criteria that would allow any reasonable person to say they are manufacturing?

MR. CHALOS: Object to the form.

THE WITNESS: So, I mean, our entire -- our entire legitimate drug supply, I mean, in this country is, you know, Pfizer and Abbott. Those are manufacturers. They don't need physician -- patient-specific practices. They are introducing a drug in interstate commerce, right, for sale, and they are subject to 505, right? They are clearly manufacturers.

MR. GIDEON: Q. Okay. I know that Pfizer

is a manufacturer and I know Abbott is a manufacturer. What I want you to do, though, is tell us what is the definition of a manufacturer. Don't just tell me a company name. That's not helpful. Tell me what the definition is.

MR. CHALOS: Object to the form.

THE WITNESS: So a -- under which law?

MR. GIDEON: Q. The --

A. Under FDAMA or not under FDAMA?

Q. The Food, Drug and Cosmetic Act of 1938, as amended, up to and including but not including the 1997 FDAMA.

A. Not including --

Q. Not including FDAMA.

MR. CHALOS: Object to the form.

THE WITNESS: So if you wanted to do that, that's what I wrote specifically in the -- that's what we wrote specifically in the 1992, 1994 compliance policy guide.

MR. GIDEON: Q. What is it?

A. Okay. And it gave certain -- that gave certain criteria, okay, that if you were engaged in -- they were not -- they were, I don't know, seven, eight, nine criteria that were part of that policy guide whereby even if you were a retail pharmacy, the agency would not

grant enforcement discretion.

Q. Okay. I'm going to ask again. What is the definition of a manufacturer? Please give me some substance to your answer instead of just telling me about things I might find somewhere else at another time.

MR. CHALOS: Object to the form. Object to the commentary.

MR. GIDEON: Q. And if you honestly can't answer --

A. No, I --

Q. If you can't answer the question, just say so.

A. I can answer this very -- I mean -- and I think I just did, right?

Q. No, you didn't.

A. Yes, I did. Well, I think I did.

If you turn to page S0338 in my report, just turn there.

Q. Okay. Why don't you read it to us.

A. Okay.

Q. What is the definition of a manufacturer?

A. So FDA -- this is where FDA -- FDA may, in the exercise of its enforcement discretion, initiate federal enforcement actions against entities, okay, and responsible persons when the scope and nature of a

the compounder?
A. Entitled?
Q. Yeah --
MR. CHALOS: Objection.
THE WITNESS: Entitled is a matter of law.
MR. GIDEON: Q. Well, let's start there.
A. Entitled is a matter of law. I see nothing in the statute that says you can't rely on a statement.
Q. You can or cannot?
A. You cannot. I see nothing that says, in the statute, if you make a statement to me, I mean, in writing, which is subject to -- what is it -- 18 U.S.C. 1001, that's a statement to a federal official.
Q. Right.
A. Federal officials are allowed to rely on statements made to them. Of course you are.
Q. Okay.
A. Let me finish the answer.
At the same time as you see in the documents, right, there was a -- there was a decision, right, that at that time, that they -- that NECC was engaged in a compounding role. And therefore, the decision was made to let the state of Massachusetts take the lead.
In fact, you know, most of the time, I have

MR. GIDEON: Q. Okay. Now, with respect to all of the material that you have looked at from 2002, did any of the FDA employees take the step to see if any of these products were covered by a valid state prescription?

A. I don't -- I don't see that. What FDA did was what you would expect FDA to do, which was, I mean, at the time there was a concern about the safety of certain products. FDA focused on the issue, and I think acted very appropriately, made sure that product was recalled. Right?

Because understand at this moment in time --

Q. What question are you answering?

A. I'm -- you are asking me about whether -- what FDA's role was.

Q. No, I didn't.

A. Yes, you did.

Q. I didn't ask that question at all. I said did they check to see whether or not there were valid prescriptions. You answered that and said there's no evidence that they did, and then you just started talking.

A. No, I didn't start talking.

MR. CHALOS: Object to the form. There's not a question.

Excuse me. Object to the form.
MR. GIDEON: That's true. There is no question, but he is just extolling something, sharing with us at a thousand bucks an hour. And I really must insist on you answering my questions.
MR. CHALOS: Don't answer. Object to the form. That's not a question. Object to the admonition.
Hang on. Let him ask a question, please.
MR. GIDEON: Q. Yeah. Now that we know they didn't check, why didn't they, if that's so important?
MR. ARBITBLIT: Object to form.
MR. CHALOS: Object to the form.
MR. GIDEON: Q. Why didn't they take the time to check and see if this volume of product was covered by patient-specific prescriptions?
MR. ARBITBLIT: Object to form.
THE WITNESS: Exactly the answer I gave you before when you cut me off. I gave you an answer.
MR. GIDEON: Q. I --
A. Yes, you did.
Q. Okay. What is the answer, then?
A. Read back what my answer was. What I said was the reason -- what FDA was doing at this time, right, was what FDA should have been focused on, which was

about. It's at schedule 5 of his report, sub (e), FDA Investigation Report, October 24, 2002 to February 10, 2003, at page 14, which is also marked as S0476.

Question No. 2 of the FDA investigation: Does the NECC continue to fill patient-specific prescriptions for each compounded product dispensed?

Answer: NECC dispenses and prepares products in bulk for administration to individualized patients pursuant to a receipt of a valid prescription from a prescriber, end quote.

MR. GIDEON: Q. Do you know if that representation by NECC was intentionally false or not?

A. I don't believe I've seen the prescription databases and the prescriptions that NECC had at the time, so I don't know that. I know it was false later on. It would have been false later on.

Q. And when did it first become false? When did the representations by NECC about getting patient-specific prescriptions first, to your knowledge, become just an utter lie.

MR. CHALOS: Object to the form.

THE WITNESS: So on -- based on the --

MR. GIDEON: Q. The question is when.

A. I understand exactly.

MR. CHALOS: Object to the form.
THE WITNESS: So based on the record that I have seen, okay?
MR. GIDEON: Q. I'm directing it to you as the witness, not a record somebody else has seen. So that's implicit.
MR. CHALOS: Object to the commentary. There's not a question pending at this point.
MR. GIDEON: Q. When? When did their representations about receiving patient-specific prescriptions become an utter lie?
MR. CHALOS: Object to the form. Misstates the record.
THE WITNESS: So the record that I have seen --
MR. GIDEON: Q. Okay. The record you've seen. We've got that.
A. But -- but --
MR. CHALOS: Object to the commentary. There's not a question pending, sir.
THE WITNESS: Hold on. I -- what I'm trying to help you get -- I mean, because the record --
MR. GIDEON: Q. Doctor, you are not helping anybody because you are --
A. I'm trying to answer your question.
Q. -- you are not answering anything.

MR. CHALOS: Objection. Argumentative.
MR. GIDEON: Q. Every response --
MR. ARBITBLIT: Let's take a break.
MR. GIDEON: Q. -- you provide, there's a long windup, and then a lot of words, and very seldom an answer.
MR. CHALOS: Objection to the form.
C.J., quit whining. Let's take a break.
MS. MARTINEZ: There's a question pending. Hold on.
MR. CHALOS: There is no question pending --
MR. ARBITBLIT: He stopped his question with a diatribe.
MR. CHALOS: There's no question pending. Let's take a break.
MR. GIDEON: We're going to get an answer to the question. The witness says he wants to answer the question --
THE WITNESS: I would like to answer the question.
MR. GIDEON: -- so let's get an answer.
MR. ARBITBLIT: Well, then reask the question and don't interrupt him when he's giving you --
MR. GIDEON: You are interrupting --
MR. ARBITBLIT: There's no question pending,

acceptable formulary under an ambulatory surgery center?
A. Usually -- no, usually medical staffs do that.
Q. Did Tennessee law permit substitution for prescriptions in calendar years 2010 through 2012?
MR. CHALOS: Object to the form.
THE WITNESS: I would assume so, but I would want to pull the statute.
MR. GIDEON: Give me No. 13.
THE WITNESS: Thank you, Don.
MR. GIDEON: This is Exhibit 1256.
(Whereupon, Exhibit 1256 was marked for identification.)
MR. GIDEON: And this comes from PCCA075 to 078. Documents produced by Pharmacy Compounding Centers of America, PCCA, produced to the PSC before we got involved in the litigation.
Q. I want you to take a moment and look at it, but I want to tell you what my specific question is.
A. Sure.
Q. And that is if NECC had complied with this policy to crimp and seal individual vials and then autoclave those individual vials for 20 minutes at 121 degrees centigrade, 15 pounds per square inch, would that have prevented the fungal outbreak?
A. I'm not going to opine on that. An infectious

disease expert can do that.

Q. Do you know whether complying with this procedure would have killed the fungi in the vials in question?

A. I have not studied that question, sir.

Q. So you do not know?

A. I have no opinion on that.

Q. You told me earlier that you knew the difference between terminal sterilization and aseptic processing.

MR. ARBITBLIT: Object to form. Mischaracterizes.

MR. GIDEON: Q. How does that mischaracterize what you said?

A. I said I can look that up pretty quickly. I didn't have it in my head.

Q. Okay. Well, the document that's in front of you right now, you have enough experience to know that what it advocates doing is terminal sterilization, correct?

A. I mean, the final stage of the product, that's what terminal means, yes.

Q. Correct. So if your ultimate production are individual vials, and those individual vials are subject to being autoclaved, that is terminal sterilization,

action, the agency will consider nine factors. You and I talked about that.

And I don't see what you're reading as one of the factors that FDA said it would consider. Am I wrong?

Q. So from the standpoint of this self-proclaimed expert in drug regulation, volume by a compounder was irrelevant to the FDA?

MR. CHALOS: Object to the form.

MR. ARBITBLIT: Object to the form. Argumentative.

THE WITNESS: So, again, I was confirmed by the United States Senate, appointed by one president, reconfirmed -- I mean, kept on by a second president, right? And I ran the agency for seven years.

So, again --

MR. GIDEON: Q. Is volume relevant or irrelevant?

A. I'm taking issue. You felt it necessary to talk about self-proclaimed.

Q. Yeah.

A. Right? You didn't need to do that. Okay?

Now let's talk about volume.

Q. Is volume relevant or not relevant?

A. I believe that volume is relevant. If you read

was sent to the New England District Office of the FDA?

A. I do know it was in receipt -- yes.

Q. You also know that the New England District Office of the FDA did not send that cease and desist order to the Massachusetts Board of Registration and Pharmacy, don't you?

A. I've read Dr. Hamburg's testimony on that. In fact, I have the exact language. Let me tell you what I know. Dr. Hamburg testified she wished there was better communication. The Massachusetts Board of Pharmacy said they became aware of it in the -- in 2012.

Q. '12?

A. Right. I think Dr. Smith testified to that, if my recollection is right.

Q. The interim commissioner, Lauren Smith, of the Massachusetts Board of Pharmacy?

A. She said the executive -- there was something I didn't quite understand. I have the testimony, let me just get it.

Q. You are free to do it if you wish, but I can tell you that the Penta deposition establishes as well that the Massachusetts Board of Registration and Pharmacy did not get the May 2011 cease and desist order until June or July of 2012.

A. I believe Dr. Hamburg -- and I want to check

or safety issue.

And what I'm trying to determine, and there's other pages of testimony, whether -- that I thought I read where FDA said to the -- said to Colorado, share this with Massachusetts. That's -- again, this testimony is the extent of my knowledge.

Q. So how does it answer the question then?

A. It --

Q. It doesn't.

A. It tells -- well, she was asked about those questions. This is the record that I have.

Q. Well, let's look at it -- I assume it's the best you can do in answering my question of whether they did or didn't share the information? They, being the FDA with the --

A. Well --

Q. Excuse me.

-- the Massachusetts Board of Registration and Pharmacy?

MR. CHALOS: Object to the form.

THE WITNESS: Actually, there's more here. This is Dr. Smith: Just to be clear, while the executive director of the Board of Pharmacy did receive notification from the Colorado Board of Pharmacy regarding the cease and desist, that was done in

on the record.

MR. GIDEON: She asked you to be quiet and you didn't.

MR. ARBITBLIT: Counsel, she asked you both equally.

MR. GIDEON: She's looking right at Dr. Kessler who just keeps talking no matter what anybody says.

MR. ARBITBLIT: That's uncalled for.

MR. GIDEON: Q. Now, one thing, in the limited amount of time you and I have together today, but I do think there will be another opportunity, is for you and I to please speak one at a time so that we can both be kind to the court reporter. Will you agree to do that?

A. I'd be happy to do that.

Q. All right. Now, I can't stop you from making a speech about the documents, so will you please do it and get it over with so I can ask a question.

A. You have added to this document on the last page information about the office of the chief counsel at FDA whose -- again, I don't want to characterize it as legal advice, but you've been advised not to go near attorney-client privilege.

I think when you are talking about the office of the chief counsel is not doing something, I'll leave

wouldn't want to walk into a firm where there's a legal dispute if I were an FDA investigator. That's not fair to the FDA investigator until they knew whether the office of the chief counsel was going to support them.

And again, I think we are very close to deliberative process here.

Q. Now, in October of the same year, pulling FDA 426106 to 107, the same month as this statement that they're not going to go back until there is a reply to the response?

A. That's not what this says. You mischaracterized that. It says: CDER is going to try to set up a conference call with Kevin Fanin and others at the office of the chief counsel next week to try and resolve this.

Somebody wants -- I mean, Regina and I were insistent that some sort of letter has to go out before we reinspect. They're trying to resolve this with their colleagues.

(Whereupon, Exhibit 1262 was marked for identification.)

MR. GIDEON: Q. The same month we have the underlying documents that reflect an outbreak of klebsiella pneumonia on multiple patients in this email that is FDA 426106 to 107 in the city of

New York. Correct?

At least 5 and up to 17 individuals exposed to klebsiella pneumonia. Three hospitalized, two with positive blood cultures, nine have been interviewed without symptoms. Symptoms -- or the exposure occurred between October 13th and 14th. The patients received an intravenous version of the drug triamcinolone, brand name Kenalog, made by NECC.

A. Could you kindly pull NECC_FDA 08550, and then zero -- 03476 on October 28th? What's the date of these?

If you can give me the October 28th documents. Go ask your question, but let's pull those documents. Ask your question.

MS. WEETER: What was the first number you said?

THE WITNESS: NECC_FDA 08550. Then I think it is 03476, but I could be wrong. But you should have it. One is an October 30th document, and one is an October 28th document.

But go ahead, ask your question.

MR. GIDEON: Q. Well, doesn't this document establish that there was a product made by NECC that was used on multiple patients? Question.

A. That's correct.

Q. Yeah.

A. But that's not -- I mean, but please do the full record here. I believe FDA went to the pain clinic and decided the pain clinic -- let's find the documents, but let me have them in front of me.

I believe FDA went and inspected the pain clinic and found the pain clinic did not have proper infectious control practices and the problem was at the pain clinic. But please pull those documents so we can have those on the record.

Q. Isn't this correct, though, you had a number of people sick, FDA knew that there was product being made and sold by NECC without patient-specific prescriptions, as confirmed by the documents that are right in front of you.

A. So, again --

Q. Simple question. Is that true or not?

A. So let's just -- so just give me the line. I haven't read this. Tell me where it says that. I'm sure you are right, but just give me the line where it says that.

Q. Well, bullet point one: At least five and possibly up to 17 individuals exposed to klebsiella pneumonia.

A. Yes.

Q. Bullet point four, it was made by NECC. Triamcinolone, also known as Kenalog.
A. Right.
Q. Correct?
A. Again, I think there's some question about the NECC product in the subsequent documents, but I'm not going to -- you know, I need those documents in front of me before testifying.
Q. Doesn't establish that there were not patient-specific prescriptions --
A. Show me where --
Q. -- covering --
A. -- says that --
Q. -- the product used on multiple patients?
MR. CHALOS: Object to form.
THE WITNESS: I'm sorry. Show me where it says that, please.
MR. GIDEON: Q. The bottom of the first page.
A. The triamcinolone was provided in a 10 multi-vial -- right? The envelope had on it a prescription --
Q. No, no, no. Don't skip it. Read it very carefully. The envelope reportedly had on it --
A. Reportedly had on it --

(Reporter requests one speaker at a time.)

MR. GIDEON: I'll read it. Quote: The envelope reportedly had on it a "prescription" for a single patient being seen at the clinic.

The clinic drew multiple doses from this single-patient-specific-vial and used this for several patients.

Doesn't that establish there were not patient-specific prescriptions for each administration of the NECC product?

A. This certainly seems to be exactly what it says. It seems to be -- there was a vial with a prescription, okay, I mean, on it, for one patient. And it looks like somebody reused this for multiple patients.

And to be honest with you, I think you have your answer on the klebsiella. Because why is somebody using a single unit for multiple patients. So somebody at the pain clinic obviously doesn't know basic infection control, but let's take a look those documents.

Q. Well, the vial doesn't have a prescription on it. The vial doesn't say anything about being for a specific patient.

A. The envelope did.

Q. The envelope reportedly had on it a prescription.

A. It says exactly what it says.

Q. Correct. Which is why I asked the question. Doesn't this make it clear, didn't FDA know that NECC was selling product that was not being used for specific patients?

MR. CHALOS: Object to the --

MR. GIDEON: Q. And not being subject to patient-specific prescriptions?

MR. CHALOS: Object to the form. Misstates the document.

MR. GIDEON: Argumentative.

Go ahead.

THE WITNESS: This --

MR. CHALOS: Object to the commentary.

THE WITNESS: And can I see my documents that I requested, please, if you can help me?

MS. WEETER: They're on my computer. I can read them. Do we need to read those or do we want to move on?

MR. GIDEON: Q. I'm going to give Dr. Kessler the opportunity to explain why you need the documents. And if you can tell us why we should spend time on it we'll do it for you. But just to

request the documents to talk about them isn't really pertinent.

A. So you don't -- you're not asking -- you didn't ask what -- whether FDA acted appropriately on this?

Q. No. I've already asked you some questions --

A. And I --

Q. I'm certain you're going to say that FDA acted in the highest standards of regulatory oversight. I expect that.

MR. CHALOS: Objection. Argumentative.

MR. ARBITBLIT: For completeness, I'll read from the document that the witness referred to, which is an October 30, 2000 email from Robert Durkin to Samia Nasr saying: It seems it was lack of aseptic technique at the clinic level with subsequent contamination of the Visipaque --

(Reporter clarification.)

MR. ARBITBLIT: -- Visipaque -- capital V-I-S-I-P-A-Q-U-E -- manufactured by GE Healthcare, end of quote.

And the page number of that -- and that's responding to a question from Nasr to Durkin on the same date. And the question is, quote: It looks like they ruled out that the problem was from NECC, triple question mark, end of quote.

So your attempts are --

MR. GIDEON: Q. We'll make that the next exhibit. Does that reflect --

MR. ARBITBLIT: Hold on.

MR. GIDEON: -- the presence --

MR. ARBITBLIT: I'll read the number so you can find it. It's NECC_FDA 08550, which is part of an 11-page document.

MR. GIDEON: Q. Does that reflect the presence of testing on the vial?

A. I have to see the -- you have to give me the document.

Q. Does it reflect testing on the vial?

A. Sounds like it's not an NECC product.

MS. WEETER: It is an NECC --

THE WITNESS: What?

MS. WEETER: They received an NECC product.

THE WITNESS: I'm sorry?

MR. GIDEON: Q. Does it reflect testing on the vial?

THE WITNESS: Could someone print that?

MR. ARBITBLIT: Object to form. What vial?

MR. GIDEON: The vial that we've spent five minutes talking about. The multi-use vial with triamcinolone in it made by NECC.

I'm just asking --
THE WITNESS: Can I see that document?
MR. CHALOS: It's on the screen.
MR. GIDEON: I'm just asking, Kaycee, does it reflect testing on the vial?
MS. WEETER: It looks like they requested samples or reports from the New York NYC DHMH, and there's no evidence in here that they had results from those --
MR. GIDEON: Hmm.
MS. WEETER: -- samples that were --
THE WITNESS: It does say these have been sent to the department's labs.
MR. GIDEON: Q. Is there anything in there reflecting that what you told me earlier should occur, which is, you go ahead and you look at this material, you get the laboratory data and determine what's in the product to see if it relates to the illness of the patient? Do you find any reflection of testing of the vial?
A. Yes. You see it says here, these have been sent to the department's labs.
Q. What's the result?
A. I'm sorry, you have to give me the record if you want me --

Q. Well, I suspected, since you asked for the documents earlier, you would have looked yourself to see if the vial was tested.

A. Hold on one second.

Q. And that's the pending question: Was the vial tested to see if it was contaminated?

A. Let me just read this.

MR. ARBITBLIT: Counsel, I think we're at the end of seven hours. In the spirit of cooperation, if the witness is willing, we'd like you to have an additional 15 minutes. You probably aren't going to think that's sufficient, I'm guessing, because we never seem to agree on that. But that's what we're offering. If you would like to continue with the questioning for an additional 15 minutes, we're willing to stay for that.

MR. GIDEON: Well, I'm happy to take the additional 15 minutes, but it won't be sufficient to complete what I intend to do today. So if -- I'll take the 15, but not with the agreement that that's it.

MR. ARBITBLIT: I wasn't asking for your agreement. I wasn't expecting it.

MR. GIDEON: What I want to understand is can I go ahead and take the extra 15, then seek permission from the magistrate to complete this deposition, or is

the 15 a "if you take this you have agreed that that's it"?

MR. ARBITBLIT: No, I was not suggesting 15 minutes and you are forever barred. You can seek what you want and we'll oppose it, and we think we're being reasonable.

MR. GIDEON: I appreciate the 15 minutes. Very gracious.

MR. CHALOS: Would 30 minutes obviate your concern?

MR. GIDEON: No. I think Dr. Kessler's lack of response to literally every question today has made it such that I've really had just a couple hours to actually ask him questions. It has been a long time since I've seen a witness this unresponsive, so I will be seeking additional time. And we'll use examples from today's deposition to attempt to convince the judge to let us have that time.

MR. ARBITBLIT: I expect that you will. And we'll probably use examples of your improper questioning in response.

MR. GIDEON: Sure. Well, I don't know what we're doing right now. He's looking at something, I don't know why, I don't know what he intends to do.

THE WITNESS: You have a question pending, sir.

MR. GIDEON: Q. Well, I asked you did they ever test the vials, which you told us was the gold standard for a response by the regulator.

MR. CHALOS: Object to the form.

MR. ARBITBLIT: Object to form.

MR. GIDEON: Q. What is the answer to that question?

A. Yes, this was tested. I'm just trying -- this was tested and I'm just trying to understand.

Q. What were the results, then?

A. I don't have the results in this document, but this was sent for testing.

Q. I know --

A. And it was concluded that there were improper infection control practices at the clinic.

Q. Okay.

MR. ARBITBLIT: May I have the computer back now?

THE WITNESS: Thank you.

MR. GIDEON: Q. Now, take a look at the exhibit that reflects the materials produced by FDA. The larger document that has the time line, the chronology that's typed.

A. Yes, sir.

Q. Can you give me the exhibit number on that